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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RADEMACHER, MARK A

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,730

Applicant(s)

MARTIN ET AL.

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☒ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "Po" in FIGS 4A-4E.

The drawings are objected to under 37 CFR 1.84(l), which requires that all drawings must be made by a process which will give them satisfactory reproduction characteristics. Every line, number, and letter must be durable, clean, black (except for color drawings), sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

In addition, the drawings include labels and verbiage that contradict the numbering referred to in the patent application. For example FIGS 4A – 4E are accompanied by headings such as "Appendix 1" and "Figure 2" "Figure 3", etc. The extraneous labels on the figures must be deleted.

The drawings are also objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second averager must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 1, line 14 an extraneous period is added to the sentence. On page 2, line 21, the applicant appears to have omitted a number between the phrase "order of" and term "mm". On page 7, line 19 it appears the letter "l" on either side of the expression Pl-Pb should comprise an absolute value symbol

Appropriate correction is required.

Claim Objections

Claim 14 is objected to because of the following informalities: The wording of the preamble is unclear because the applicant introduces and apparatus and then recites a method, which is confusing.

The Office suggests that the applicant amend the preamble of claim 14 to read:

"A method for presenting a respiration signal indicative of the patient's breathing pattern in an apparatus adapted to provide a flow of pressurized air to a patient, the method comprising:"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6-13, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "said output signal" in line 9. There is insufficient antecedent basis for this limitation in the claim. Dependent claims 7-13 incorporate the antecedent defect of parent claim 6.

Claim 23 recites the limitation "said duration" in line 1. There is insufficient antecedent basis for this limitation in the claim. Dependent claim 24 incorporates the antecedent defect of parent claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, 19, 20 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,246,995 to *Sullivan et al.*

Sullivan et al disclose all of the *structural* elements recited in the apparatus claims.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

"[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original). MPEP 2114.

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Accordingly, the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *See, In re Hutchison*, 69 USPQ 138 (CCPA 1946). Accordingly, the applicant's recitation of functions which the control unit, adjusting circuit, averagers and pressure sensor are "adapted to" (or like language) performed not entitled to any patentable weight.

Sullivan et al disclose a respiratory apparatus a blower (air blower 21), a patient interface (nose mask 12), a control unit having and adjusting circuit and a first averager (amplifier/filter/processor unit 26) and a display adapted to show the breathing signal. The display that *Sullivan et al* disclose takes the form of a record created by the processor/recorder of the breathing signals from the microphone. These processed signals are recorded as a time chart or a table that is reviewed by a physician. In fact and example of such a display is shown in FIG 2a. See column 6, lines 5-8 and column 8, line 61 through column 9, line 6.

With respect to claim 2, *Sullivan et al* disclose a pressure sensor (snoring detection means 22 having pressure detection means and microphone 11; see column 9, lines 66-68 and column 14, lines 45-48).

With respect to claim 3, *Sullivan et al* disclose a baseline generator (filter amplifier/processor 26, which generates a control signal, among other functions; column 11, lines 58-61).

Claims 4-5 do not add additional structural limitations to the parent claims. Moreover, FIGS 7 and 8 and accompanying discussion describe the functionality recited in these claims.

Similarly, *Sullivan et al* disclose all of the structural limitations recited in claims 6-13.

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The respiratory apparatus described by Sullivan includes a blower, a patient interface, a control unit coupled to either the patient interface or the blower and that includes a signal processing unit and adjusting circuit, and a display.

Claims 7-13 do not recite additional structural elements are therefore are also anticipated by the *Sullivan et al* disclosure. In addition, the *Sullivan et al* disclose the functional limitations therein. See FIGS 7 and 8 and the accompanying discussion.

Sullivan et al anticipate method claims 14-17, 19, 20, 24, 25 and 26-29 as well. *Sullivan et al* disclose a method for presenting a respiration signal including the steps of determining a parameter within the device related to the flow of pressurized air and the breathing of the patient, adjusting the parameter based on a baseline signal to generate a respiration signal within a predetermined range based on an average value of the respiration signal. See *Sullivan et al*, FIGS 7 and 8 and accompanying discussion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 21-23 and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over *Sullivan et al*, and *Sullivan et al* in view of US patent no. 4,957,107 to *Sipin*.

Sullivan et al disclose a method including the steps of determining a parameter with the device related to the flow of pressurized air and the breathing of the patient, adjusting the signal based on a baseline signal to generate a respiration signal within a predetermined range based on

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the respiration signal and displaying the signal. *Sullivan et al* also disclose the steps of determining an absolute difference between said average value and the baseline signal and if the absolute difference is less than a first threshold then setting said baseline signal to the average value. See *Sullivan et al* FIGS 7 and 8, and the accompanying discussion.

Sullivan et al do not expressly disclose that the average value is calculated over a period of about 12 seconds, *Sullivan et al* do disclose that the average value is calculated over 4 and 64 inhales. See FIG 8.

Sipin discloses a gas delivery apparatus having the same general structure as that disclosed by *Sullivan et al*. The apparatus includes logic that calculates an average flow rate over time periods ranging from 0.3 seconds to 10 seconds. See Table 1, B(3) and (4), and D(3) and (8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the *Sullivan et al* method and apparatus to take averages over time periods shorter than a typical breath of a person, and for the particular time periods specified in claims 18, 21-23 and 30.

One of ordinary skill in the art would have been motivated to make this modification in order to optimize the responsiveness of the method and apparatus disclosed by *Sullivan et al*.

Optimizing a variable in a system, such as the period over which an average is calculated, has been held to be obvious in light of prior art that disclose the general working range of the variable.

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For example, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%). *See also In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). *See also, Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patent nos. 5,199,424, 5,148,802 and 5,740,795 to *Sullivan et al*, Sanders et al and *Brydon* disclose respiratory apparatuses having the same structure and substantially the same functionality as that claimed by the applicant.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842.


The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR

January 6, 2003


GLENN K. DAWSON
PRIMARY EXAMINER